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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------|
| 10/004,867 | 12/07/2001 | Serge Beaudoin | 004208.00034 | 9077 |
| 22907 | 7590 | 05/19/2004 | | |
| BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001 | | | | |
| | | | EXAMINER TRUONG, TAMTHOM NGO | |
| | | | ART UNIT 1624 | PAPER NUMBER |

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/004,867 | Applicant(s) BEAUDOIN ET AL. | |
| | Examiner Tamthom N. Truong | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,11,13,14 and 22 is/are rejected.
- 7) ☒ Claim(s) 4, 10, 12, and 15-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Applicant's amendment of 02-20-04 has been considered. However, applicant's argument has not been found persuasive, and thus, has not overcome the previous rejections of 112/1st paragraph. Therefore, said rejections are maintained herein for claims 1-3, 5-9, 11, 13, 14, and 22.

Claims 1-22 are pending.

Claim Rejections - 35 USC § 112

1. **Lack of Written Description** (for spiro-cycle): Claims 1-3, 5-9, 11, 13, 14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant asserted that the limitation of R⁵ and R⁶ forming a ring (i.e., spiro-cycle) would only be a generic description, and thus, would not need a specific description of the arrangement of atoms. However, the general reaction schemes provided do not even allow a step where R⁵ and R⁶ can form a ring. Applicant contended that the spiro-cycle could be made from a known reaction (as described in Schemes 1 and 2 in applicant's remark). However, the claimed compound is more complicated than that of the cited Schemes 1 and 2. If one were to follow such a scheme, would one need to form the spiro-cycle before adding the group of -NH-SO₂-R⁴, or after adding said group? From

the generic reaction schemes provided and the preferred embodiment, there appears to have no description of a spiro-cycle.

2. **Enablement** (for spiro-cycle): Claims 1-3, 5-9, 11, 13, 14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed in the paragraph above, there is no guidance in the specification that would lead to a spiro-cyclic compound. The reference cited in applicant's remark does not sufficiently guide the skilled chemist in the making and using spiro-cyclic compounds. Note, the process for making a spiro-cycle requires an additional step that is not taught by the instant disclosure. In an unpredictable art such as chemistry, an additional step could result in an unforeseen by-product, which in turn would give an undesired impurity. Therefore, undue experimentation would be inevitable to make a spiro-cycle claimed herein.

3. **Lack of Written Description:** Claim 22 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Although claim 22 has been amended to "*a method for treating a potassium channel mediated cell proliferative disorder*", it still does not indicate which disorder gets treated. The phrase "*cell proliferative disorder*" covers an array of disorders including both cancerous and non-cancerous ones. It even includes embryo genesis, in which case, the "*method for treating a*

potassium channel mediated cell proliferative disorder” would ultimately include a method for inhibiting embryo genesis as well. Therefore, without a written description of what is intended for a “*cell proliferative disorder*”, the scope of claim 22 has indefinite metes and bounds.

4. **Enablement:** Claim 22 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since there is no written description on which “*cell proliferative disorder*” can be treated, it would take undue experimentation for one skilled in the art to practice the claimed method.

Claim Objections

5. Claims 4, 10, 12, and 15-21 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1624

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

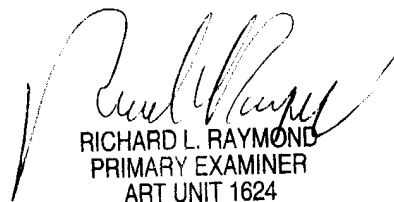
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong

May 13, 2004



RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624